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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,587	03/26/2002	Craig Stephen Harris	P 0284168	6402

909 7590 08/11/2003

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9
EXAMINER

HAMPTON HIGHTOWER, PATRICIA

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,587

Applicant(s)

HARRIS ET AL.

Examiner

Patricia Hightower

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- ☐ Interview Summary (PTO-413) Paper No(s) _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Information Disclosure Statement

The information disclosure statement filed December 04, 2001 has been considered and has been made of record.

Response to Amendment

The preliminary amendment filed December 04, 2001 is acknowledged; claims 1-14 are presently pending.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it does not contain "headings" in the arrangement of the specification.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

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REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is considered to be rendered indefinite because in denoting the therapeutic peptide, the applicants have not defined the following substituents "Phv, Papa". Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinz et al (USP 5,049,651).

Heinz et al (USP 5,049,651) discloses a process for the solid phase post-condensation of (co)polyamides which contain small amounts of lysine components and about equivalent amounts thereto of a polycarboxylic acid incorporated; wherein melt polycondensation from at least one lactam, diamine/dicarboxylic acid mixtures, nylon salts or a derivative thereof or aminocarboxylic acids or derivatives thereof, and a lysine polycarboxylic acid reactant, wherein the (co)polyamide contains 0.1 to 2.0% by weight of lysine segments and about equivalent amounts thereto of polycarboxylic acid segments which anticipates the claimed invention. See abstract; claims 1-4; cols. 1-5; the examples.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kates et al (*Biopolymers Peptide Science* 47(5), 1998, pages 365-380, "High-Load" *Polyethylene Glycol-Polystyrene (PEG-PS) Graft Supports for Solid-Phase Synthesis*).

Kates et al discloses and describes the introduction of polyethylene glycol into solid phase supports to increase the hydrophilicity of the support, ornithine was added to amino functionalised polystyrene wherein the ornithine is differently protected on each amino group and one protecting group is removed to allow for bond formation with polyethylene glycol (PEG) by way of a carboxylic acid group which is thereby introduced

into the chain, this increases the number of available linking groups, resulting in resins with higher loadings (0.3-0.5 mmol/g); which anticipates the claimed method for preparing a solid support material for performing a chemical reaction comprising the steps of (i) reacting an amino functionalised solid material with a carboxylic acid having at least two similarly protected amino groups to form amide bonds between them, (ii) removing the protecting groups in a single step, (iii) optionally, repeating steps (i) and (ii) one or more times using the product from the preceding step as the amino functionalised solid material and (iv) connecting a linkage agent to at least some of the free NH₂ groups of the product. See abstract; page 366, introduction, materials and methods; page 367, preparation of PEG-PS (polyethylene glycol – polystyrene); page 368 solid-phase peptide synthesis; page 369 Exploratory PEG-PS Resins; pages 370-378.

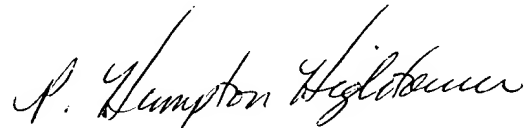
Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. These references are cited to show the state of the art of peptide compounds/derivatives, solid-phase dendrimer synthesis, solid-phase peptide synthesis, preparation of resin-bound cyclic peptides; Sledeski, Wells, Lebl, Edwards, Luke and Toth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Hightower whose telephone number is (703) 308-2434. The examiner can normally be reached on M-F from 9:30 A.M. - 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



P. Hightower:ph
August 7, 2003



P. Hampton Hightower
Primary Examiner
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